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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WALICKA, MALGORZATA A	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,828	THOMAE ET AL.	
	Examiner	Art Unit	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *3-6,8,10,12 and 15-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7,8,11,13,14 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/06/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: sequence alignment used in 102 rejection.

The Response to Restriction Requirement filed August 23, 2006 is acknowledged. Claims 1-19 are pending; claims 1, 2 and 19 all in part, and claims 7, 9, 11, 13 and 14 in their entirety, related to variant of SEQ ID NO: 5 having substituted positions 173, 287 and 306, elected without traverse are under examination. Claims 3-6, 8, 10, 12, 15-18 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions.

DETAIL ACTION

1. Election/restriction

Applicant's election of group I, in the reply filed on August 23, 2006 is acknowledged. The election was made without traverse.

Group I comprises claims 1, 2, and 19 all in part and claims 7, 11, 13 and 14. The claims are directed to DNA encoding human arsenic methylase SEQ ID NO: 5 (reference sequence) wherein amino acids residues 173, 287 and 306 are variants.

2. Priority

The priority of the claims under examination to the provisional application 60/463,114 filed April 15, 2003 has been granted.

3. Objections

The specification is objected to for a vague description of the term "arsenic methyltransferase (ASMT) nucleic acid sequence". The specification on page 6 line 24

describes the arsenic methyltransferase nucleic acid sequence as including a nucleotide sequence variant and nucleotides flanking the sequence variant. One having skills in the art reads this description as indicating that Applicants understand by the ASMT a large genus of nucleic acid sequences. This genus, by the virtue of what is disclosed comprises a subgenus of a nucleotide sequence variants and variants of nucleotides flanking the genomic DNA of SEQ ID NO wherein said variant sequences have substitutions of the nucleotides 8011, 12327 and 23936 of exons of SEQ ID NO: 1 and also substitiutions of nucleotides in the regions flanking these encoding regions. Taking into account the description of ASMT nucleic acid sequence of page 6 line 24, one having skills in the art is confused how a sequence that is to be changed at positions 8011, 12327 or 23936 may be only 10 nucleotides in length. In addition it is confusing how a sequence that is only 10 nucleic nucleotides long may encode an enzyme having ASMT activity.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors in the specification of which applicant may become aware.

4. Rejections

4.1. 35 USC section 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 2, 7, 9, 11, 13-14 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Firstly, claims 1- 2, 7, 9, 11, 13-14 and 19 are rejected because the recitation "comprises a nucleotide sequence variant in position X of SEQ ID NO" is confusing. Applicants disclose that nucleotides in the quoted positions are changed, making variants of SEQ ID NO: 1. Applicants do not disclose sequences that comprise in quoted position an insertion of any variant nucleotide sequence.

Secondly, claims 1 and dependent claims as well as claim 19 are confusing in recitation "said nucleic acid molecule is at least ten nucleotides in length" and in recitation "comprises a nucleotide sequence variant at a position selected from the group consisting of position 8011, 12327 and 23936 of SEQ ID NO: 1". One having skills in the art is confused how a sequence that is to be changed at positions 8011, 12327 or 23936 may be only 10 nucleotides in length. In addition, it is confusing how a sequence that is only 10 nucleic nucleotides long may encode an enzyme having ASMT activity.

The specification on page 6 line 24 describes the arsenic methyltransferase (ASMT) nucleic acid sequence as including a nucleotide sequence variant and nucleotides flanking the sequence variant. One having skills in the art reads this description as indicating that Applicants understand by the ASMT a large genus of nucleic acid sequences. This genus, by the virtue of what is disclosed comprises a subgenus of a nucleotide sequence variants and variants of nucleotides flanking the

genomic DNA of SEQ ID NO wherein said variant sequences have substitutions of the nucleotides 8011, 12327 and 23936 of exons of SEQ ID NO: 1 and also substitiutions of nucleotides in the regions flanking these encoding regions. Taking into account the description of ASMT nucleic acid sequence of page 6 line 24, one having skills in the art is confused how a sequence that is to be changed at positions 8011, 12327 or 23936 may be only 10 nucleotides in length. In addition it is confusing how a sequence that is only 10 nucleic nucleotides long may encode an enzyme having ASMT activity.

On page 7, line 18 of the specification, Applicants describe "nucleic acid of the invention" as having at least about 8 nucleotides in length and up to 1000 nucleotides in length. This "nucleic acid of the invention can be in sense or antisense orientation and can be complementary to the ASMT reference sequence (e.g., SEQ ID NO: 2 and SEQ ID NO: 4 ['e.g.' suggests other reference sequences; what are they?], and can be DNA, RNA, or nucleic acid analog." This description is read by those having skills in the art as indicating that Applicants intend to claim probes, primers and antisense oligonucleotides for identification and inhibiting expression of SEQ ID NO: 1 having variant nucleotides.

On the basis of what is taught on page 7 of the specification it is assumed for examination that the claims are directed to fragments of SEQ ID NO: 1 wherein said fragments comprise variant nucleotide in positions 8011, 12327 or 23936.

Claim 19 is rejected as totally not understandable in recitation "at least ten nucleotides in length" and "any combination of coding sequences, intron sequences, 5' untranslated sequences or 3' untranslated sequences. It is totally not understandable

how a 10 nucleotide sequence may comprise any combinations of sequences that are several hundred nucleotides or thousand nucleotides in length.

4.2. 35 USC section 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4.2.1. Lack of written description

Claims 1, 2, 7, 9, 11, and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a large genus of DNA molecules for which neither the function nor structure is sufficiently described. It is not known what is the function of nucleic acid molecule comprising an ASMT nucleic acid sequence. Furthermore, the structure of the claimed nucleic acid is not described in an identifying way. The current language "variant in positions 8011, 12324 and 23936" without an identifying, explicit nucleotide sequence comprising these positions, i.e., without referring to fragment of SEQ ID NO: 1 is referring to any nucleotide sequence one can think of.

Claim 19, in addition, is directed to any nucleic acid molecule comprising fragments of genomic DNA of any ASMT wherein said DNA is not identified by any nucleotide sequence. The claim suffers from a complete lack of written description of structure and function.

Furthermore, Applicants disclosed only allelic variants of human ASMT having the genomic DNA of SEQ ID NO: 1. Applicants have not disclosed any ASMT, which may be considered a variant of SEQ ID NO:1 absent the description "allelic variant ".

In conclusion, because of lack of description of function of the claimed polypeptides and their compositions, one of skills in the art is not convinced that Applicants were in possession of the claimed invention at the time the application was filed.

4.2.2. Scope of enablement

Claims 1, 2, 7, 9, 11, and 19 are rejected under 35 O.K. 112, first paragraph, because the specification, while being enabling for nucleic acid molecules that are allelic variants of SEQ ID NO: 1 having nucleotides in positions 8011, 12327 and 23936 changed, does not reasonably provide enablement for any nucleic acid molecule that is at least ten nucleotides in length and comprises nucleotide sequence variants at position 811, 1227 and 23936 of SEQ ID NO or comprises at least two nucleotide sequence variants within any combination of coding sequences, intron sequences, 5' untranslated sequences and 3' untranslated sequences of any ASMT.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broader than the enablement provided by the disclosure with regard to the large number of polypeptides that are encompassed by the scope of the claims, as well as polypeptides that are involved.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Otherwise, undue experimentation is necessary to make the claimed invention. Factors to be considered in determining whether undue experimentation is required, are summarized *In re* Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the nature of the invention, (b) the breadth of the claim, (c) the state of the prior art, (d) the relative skill of those in the art, (e) the predictability of the art, (f) the presence or absence of working example, (g) the amount of direction or guidance presented, (h) the quantity of experimentation necessary.

The nature and breath of the claimed invention encompasses any polynucleotides from any natural or man-made source, or constructed, having some unknown relationship to any ASMT genomic DNA or to ASMT genomic DNA of SEQ ID NO: 1.

While methods of gene cloning and manipulating DNA sequences are well known in the relevant art, and skills of the artisans highly developed, to obtain the claimed invention involves experimentation with a zero probability of success absent

teaching the function and structure of the claimed DNA molecules; see the above rejection for lack of written description. In result, one skilled in the art who wants to make and use the claimed invention is left with experimentation which is undue.

4.3. 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Lin S. et al, (A novel S-adenosyl-L-methionine:arsenic (III) methyltransferase from rat liver cytosol, J. Biol. Chem. 2002, 277, pp. 10795-10803, enclosed in IDS), and Strausberg R. L. et al. (Generation and initial analysis of more than 15,000 full-length human and mouse cDNA sequences, Proc. Natl. Acad. Sci. USA, 2002, 99, pp. 16899-16903).

The articles disclose the same enzyme from rat and mouse. The amino acid sequence of both prior art ASMTs anticipate the genus of claim 13; see the enclosed sequence alignments A and B with underlined positions 173 and 287.

5. Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is

(571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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